UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

CHARLES SEIFE, Plaintiff, *v.* FOOD AND DRUG ADMINISTRATION and DEPARTMENT OF HEALTH AND HUMAN SERVICES, Defendants.	Case No. 1:17-cv-03960 June 21, 2017

MEMORANDUM IN SUPPORT OF PLAINTIFF'S
MOTION FOR PARTIAL SUMMARY JUDGMENT

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PRELIMINARY STATEMENT

This action under the Freedom of Information Act (FOIA) challenges the refusal of the Food and Drug Administration (FDA) and the Department of Health and Human Services (HHS) to expedite processing of a limited and specific request for information about one of the most controversial drug approvals in FDA history—the approval of Exondys 51 (generic name eteplirsen) to treat the rare and fatal childhood illness Duchenne Muscular Dystrophy (Duchenne). That approval received massive media attention after it was granted over the unanimous objection of the FDA's scientific advisory committee and the FDA's scientific review team, which each independently found insufficient evidence that the $300,000 per year drug was effective.

Plaintiff Charles Seife is a public health journalist seeking information he sorely needs to report on a continuing debate over the approval of Exondys 51 and whether it was based on faulty clinical trials and undue industry influence. Seife needs this information to report in a timely manner on the institutional integrity of the FDA. Its disclosure will also have a real-world impact on families of young boys affected by Duchenne who are at risk of severe financial harm due to high co-pays and the failure of insurance companies to cover the drug, which may be no better than a placebo. Additionally, the information is vitally needed to inform current public debate over the FDA's pathway for "accelerated approval" of drugs like Exondys 51, debate over regulations required by the recently-enacted 21st Century Cures Act, and the upcoming debate over re-authorization of the Prescription Drug User Fee Act (PDUFA) later this year. The information is directly relevant to Seife's potential follow-up reporting on the European Union's review of a pending request for approval of Exondys 51. Finally, this information has a substantial possibility of affecting the financial survival of the company that manufacturers

Exondys 51, Sarepta Therapeutics (Sarepta). In short, there is a clear and compelling need to expedite the disclosure of this information.

Under FOIA, agencies must expedite their processing of requests when such a compelling need for disclosure exists. 5 U.S.C. § 552(a)(6)(E)(i). In making his request, Seife detailed the multiple reasons why expedited processing was required because the information he seeks concerns pressing issues currently being debated by the American public, and delay will significantly compromise the public interest in multiple respects. Defendants refused. Indeed, more than six months after receiving Seife's request, they have not even *begun* processing it. Neither the FDA nor HHS has yet indicated when processing will begin, much less be completed.

Seife now moves for partial summary judgment on his claim that defendants have illegally refused to expedite the processing of his request (Count I). By this motion, he seeks an order requiring them to do so, and specifically (1) requiring defendants to provide a full written response to the request within ten days, and (2) setting a status conference within twenty days to establish a schedule for the expedited release of the requested information on a rolling basis. In light of the time-sensitive nature of his FOIA request, Seife also respectfully requests the Court expedite consideration of this motion pursuant to 28 U.S.C. § 1657(a).

STATEMENT OF FACTS

I. FDA'S APPROVAL OF EXONDYS 51

On September 19, 2016, the FDA approved Exondys 51, a drug manufactured by Sarepta for the treatment of a subtype of Duchenne. Kenney Decl., Ex. P, 2-10. Duchenne is a neuromuscular disorder that causes progressive muscular degeneration in affected young boys and results in death from respiratory or cardiac failure. Kenney Decl., Ex. F, 3. Exondys 51 is

the only disease-modifying treatment approved for Duchenne in the United States. *Id.* Sarepta charges $300,000 per year or more to those taking Exondys 51. Kenney Decl., Ex. M.

The approval of Exondys 51 set off a "civil war" within the FDA. Kenney Decl., Ex. P, 2-10. Sarepta's early reports from clinical trials had prompted patient advocates, doctors, over one hundred members of Congress, and the public to fiercely lobby for approval. *Id.* at 2-15, 19, 30-34, 43-47; Kenney Decl., Ex. G, 24-25; Kenney Decl., Ex. L. However, a head scientist on the FDA review team found that one of the principal studies of the drug, Study 201/202, was seriously flawed. Kenney Decl., Ex. I, 13-17.

Sarepta's Study 201/202 was based on the hypothesis that Exondys 51 would cause an increase in dystrophin level in patients with Duchenne caused by a particular mutation. Kenney Decl., Ex. I, 3, 7, 11-17. Certain FDA reviewers concluded that the results from Study 201/202 were based on faulty analysis and technique. *See id.* at 13-17. Once the data were reanalyzed by these reviewers, there was no statistically significant increase in dystrophin levels associated with treatment with Exondys 51. *Id.*; Kenney Decl., Ex. J, 12-18. Yet, at various times, Sarepta announced that Study 201/202 was greatly successful, though the FDA's Acting Chief Scientist would later say that "Sarepta's misleading communications led to unrealistic expectations and hope for [Duchenne] patients and their families." Kenney Decl., Ex. F, 27.

Pressure to approve the drug ran high in the wake of the company's statements regarding Study 201/202. The FDA staff charged with reviewing Exondys 51 received thousands of emails from the public urging approval, including graphic hate mail for their delay in so doing. *See* Kenney Decl., Ex. G, 24-25. An FDA Advisory Committee meeting regarding Exondys 51 lasted eleven hours and featured fifty-one speakers in favor of approval and one against. Kenney

Decl., Ex. P, 14-15. Shouting matches broke out at the meeting when the independent experts tasked with examining the efficacy of the drug publicly voted against accelerated approval. *Id.*

After the Advisory Committee meeting, the FDA requested that Sarepta submit additional data from muscle biopsies of trial participants in an ongoing trial, Study 301. Kenney Decl., Ex. G, 7-8. These additional data failed to show the large increases in dystrophin levels that proponents of the drug expected. *Compare* Kenney Decl., Ex. I, 39-41 (noting a "minute" increase in dystrophin levels); *with id.* at 17 (noting proponents analyzed Study 201/202 to show a mean increase of 10 percent).

Lacking evidence that the drug was effective, FDA reviewers in the Division of Neurology Products, the Office of Biometrics, the Office of Clinical Pharmacology, the Office of Drug Evaluation-I, and the Office of New Drugs unanimously recommended against its approval. *Id.* at 17. The Director of the Center for Drug Evaluation and Research (CDER), Dr. Janet Woodcock, then took the extraordinary step of overruling her staff and recommending approval of the drug. Kenney Decl., Ex. H. Indeed, according to the Acting Chief Scientist within the FDA, Dr. Luciana Borio, the decision by Dr. Woodcock could be the first time in FDA history that a Center Director had ever overruled a review team (and an advisory committee) based on an assessment of a drug's efficacy. Kenney Decl., Ex. F, 15.

The Director of the Office of Drug Evaluation-I within the Office for New Drugs, Dr. Ellis Unger, was so alarmed by Dr. Woodcock's action that he appealed the approval. Kenney Decl., Ex. G. Rumors abounded that Dr. Woodcock had succumbed to external influence, and she has admitted to being worried about Sarepta's "capitaliz[ation]" if the drug were not approved. Kenney Decl., Ex. F, 17; Seife Decl. ¶ 6. Dr. Unger urged that, on the available data, the drug was an "elegant placebo" that would give families "false hope in exchange for suffering

and hardship." Kenney Decl., Ex. G, 22. He also pointed out that Exondys 51 would create a "certain" risk of side effects, such as a new risk of infection and even death, because it is often administered by an indwelling catheter, and many Duchenne patients are on concurrent chronic corticosteroids. *Id.* at 21-22.

The scientific dispute regarding approval went to an appeal committee. Kenney Decl., Ex. F. That committee concluded that a substantive scientific review was warranted. Kenney Decl., Ex. F, 3, 27-28. The Acting Chief Scientist of the FDA, Dr. Borio, also informed then-FDA Commissioner, Dr. Robert Califf, that she concurred with Dr. Unger that the evidence was insufficient to support accelerated approval of Exondys 51. *Id.* at 26-27. Commissioner Califf, however, deferred to Dr. Woodcock. Kenney Decl., Ex. E. He approved Exondys 51 while calling for the retraction of the published results of the discredited Study 201/202 and stating that flaws in the design and implementation of the clinical trials "made it impossible to use much of the resulting trial data as reliable evidence in regulatory decision-making, including for reasonable extraction to clinical care." *Id*. at 5 & n.28.

The FDA's dispute became public. Shortly before approval was announced, the review team's chief scientist in the neurology products division quit the agency. Kenney Decl., Ex. P, 4-5, 11-13. In addition, the FDA took the extraordinary step of posting documents concerning the dispute, including Dr. Woodcock's memo, Dr. Unger's appeal, Dr. Borio's review, and Dr. Califf's decision, among others. Kenney Decl., Exs. E-J. The FDA last updated its website on these documents on October 26, 2016.[1]

[1] *See* Food & Drug Administration, *Drug Approval Package: Exondys 51 Injection (eteplirsen)*, https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/206488_TOC.cfm (Oct. 26, 2016).

The highly irregular approval process generated widespread media attention. It was covered by *Forbes*, *The Washington Post*, *The New York Times*, *NPR*, *STAT News* (a news site run by the *Boston Globe*), and other mass media outlets. Kenney Decl., Ex. P, 2-47. A Lexis Nexis news search for the term "eteplirsen" turned up over 2272 articles about the drug between January 1 and November 20, 2016. Kenney Decl., Ex. A. A Lexis Nexis news search for the same term in the period from December 5, 2016 to February 3, 2017 identified over 150 more articles on the drug. Kenney Decl., Ex. C, n.1. It is an issue of continuing controversy. The filing of Seife's complaint in this case, alone, significantly affected Sarepta stock price according to media reports. Kenney Decl., Ex. R.

Due to the controversial approval and significant questions over the drug's efficacy, several insurance companies have declined to cover the $300,000 plus annual cost of the drug. Kenney Decl., Ex. P, 25-29, 55-56, 66-68; Kenney Decl., Ex. M. Even where insurance companies cover the drug, families may have high deductibles or high prescription co-pays. Kenney Decl., Ex. M. Because Exondys 51 is the only disease-modifying Duchenne treatment approved in the United States, some families may be going deep into debt to pay for it, risking foreclosure and bankruptcy. *Id.*; Kenney Decl., Ex. F, 3.

II. SEIFE'S FOIA REQUEST

Plaintiff Charles Seife is a Professor of Journalism at New York University and a freelance journalist known for his exposés of flaws in the FDA's drug-approval process. Seife Decl. ¶¶ 1-2; Kenney Decl., Ex. O. When Seife learned that Exondys 51 won accelerated approval over the unanimous opposition of the review team, he decided to investigate. Seife Decl. ¶ 4. He discovered from confidential sources that Dr. Woodcock's deputy may have had a conflict of interest based on a professional relationship with the former Chief Medical Officer and present CEO of Sarepta, Edward Kaye, and that this relationship may have improperly

influenced the approval process. Seife Decl. ¶¶ 5-6. The sources also suggested that Dr. Woodcock may have had improper contact with Sarepta employees, and that she may have taken Sarepta's finances into account in approving the drug, despite her insistence that she did not. Seife Decl. ¶ 6; Kenney Decl., Ex. E, n.23. His sources further indicated that the studies on which approval was based were unsound. Seife Decl. ¶ 7.

Seife decided to file a FOIA request for information he needed to report on the controversy, and his sources helped identify documents he should request. *Id.* ¶ 8. Seife also anticipated that the information he requested would be critically relevant to debates over the then-pending (now passed) 21st Century Cures Act, which requires implementing regulations, as well as to potential changes to the accelerated drug approval process by the Trump Administration and the re-authorization of the Prescription Drug User Fee Act (PDUFA) scheduled for this year. *Id.* ¶ 17. Seife filed his FOIA request on December 6, 2016, seeking six discrete categories of documents. Kenney Decl., Ex. A. Seife also requested expedited processing under 5 U.S.C. § 552(a)(6)(E) and submitted hundreds of pages of documentation supporting the urgency of a prompt response. Kenney Decl., Ex. A.

Under FOIA, agencies must expedite processing of requests for information when there is a "compelling need" for disclosure. 5 U.S.C. § 552(a)(6)(E)(i)(I). In fiscal years 2014 and 2015, the FDA granted only two requests for expedited processing out of the hundreds it received.[2] Seife's request for expedited processing was denied without reason, but only after Seife, though

[2] Both requests took over four hundred days to grant. U.S. Dept. of Health and Human Services, *HHS Fiscal Year 2015 Freedom of Information Annual Report*, https://www.hhs.gov/foia/reports/annual-reports/2015/index.html (Feb. 5, 2016); U.S. Food and Drug Administration, *Freedom of Information Annual Report 2014*, https://www.fda.gov/RegulatoryInformation/FOI/FOIAAnnualReports/ucm446542.htm (May 21, 2015).

his attorney, cajoled the FDA into responding at all. Kenney Decl., Ex. B; Kenney Decl. ¶¶ 23-24.

Seife promptly appealed the denial on February 6, 2017, submitting several hundred more pages documenting the ongoing controversy surrounding the approval of Exondys 51 that justified expedited treatment. Kenney Decl., Ex. P, 53-84. For instance, Seife cited a December 23, 2016 article published in the *Wall Street Journal* describing Dr. Woodcock's conduct with approval. *Id.* at 72-73. Seife also submitted a letter from Dr. Aaron Kesselheim, a member of the Advisory Committee that voted against the approval of Exondys 51 and an Associate Professor of Medicine at Harvard Medical School. Kenney Decl., Ex. M. Dr. Kesselheim supported the request for expedition, explaining that there was a "compelling need" for disclosure of the information sought by Seife because of the impending harm to patients and their families. *Id.* He also noted that potential flaws in the approval process that the requested information could reveal would be relevant to the European Medicine Agency's review of Exondys 51, to be completed within roughly 210 days after its submission in late December 2016. *Id.*; Kenney Decl., Ex. P, 74-81. Seife finally mentioned the potential financial impact disclosure of the requested documents could have on Sarepta. Kenney Decl., Ex. C; Seife Decl. ¶ 18.

Seife had to wait until April 25, 2017 before his appeal was denied. Kenney Decl., Ex. D; Kenney Decl. ¶ 40. During this period, his attorney exchanged at least ten emails with HHS, which constantly responded that the issue of expedition would be decided "soon." Kenney Decl. ¶¶ 25-39. When she finally threatened litigation, the FDA denied the request to expedite. Kenney Decl. ¶¶ 38-40. It cited a "steady decline" in media coverage of the approval, Seife's own delay in filing the FOIA request, and the FDA's prior release of 2000 pages of relevant documents as its grounds for refusing to expedite. Kenney Decl., Ex. D. Neither the FDA nor

HHS has provided a timeline for a response, let alone for production of the documents requested six months ago. Seife Decl. ¶ 13; Kenney Decl. ¶ 42.

ARGUMENT

I. THIS COURT SHOULD EXPEDITE CONSIDERATION OF SEIFE'S MOTION FOR PARTIAL SUMMARY JUDGMENT

Selfie respectfully requests the Court expedite consideration of this motion under 28 U.S.C. § 1657 because his right to expedited processing under FOIA is, by its very nature, time-sensitive. Section 1657 empowers courts to expedite actions where there is "good cause" to do so, *i.e.*, there is a "factual context that indicates that a request for expedited consideration has merit." *Id.* Such good cause plainly exists here.

Freedom of information is a "structural necessity in a real democracy." *Nat'l Archives & Records Admin. v. Favish*, 541 U.S. 157, 172 (2004). But public awareness promoted by FOIA is of little value if disclosure is not timely. *Elec. Privacy Info. Ctr. v. Dep't of Justice*, 416 F. Supp. 2d 30, 40 (D.D.C. 2006). Under FOIA, an agency must thus determine within twenty days whether to comply with a request for records. 5 U.S.C. § 552(a)(6)(A)(i). Congress explicitly recognized the harm caused by delay—given FOIA's objective to make information available in a timely manner, it declared agency delay to be "tantamount to denial." H.R. Rep. No. 93-876 (1974), *reprinted in* 1974 U.S.C.C.A.N. 6267, 6271. FOIA amendments in 1996 thus created a statutory right to "expedited processing" of certain FOIA requests, requiring agencies to respond within ten days whenever there is a "compelling need" for the information requested. 5 U.S.C. § 552(a)(6)(E)(ii)(I). This requirement "underlined Congress' recognition of the value in hastening release of certain information." *Edmonds v. FBI*, 417 F.3d 1319, 1324 (D.C. Cir. 2005).

Because "stale information is of little value," courts too "have a duty" to prevent delays that "violate the intent and purpose of FOIA." *Payne Enter. v. United States*, 837 F.2d 486, 494 (D.C. Cir. 1988) (internal citations and quotations omitted). Though agencies routinely flout FOIA's statutory deadlines, so long as FOIA remains the law, courts "cannot repeal [FOIA deadlines] by a construction that vitiates any practical utility [they] may have." *Fiduccia v. United States Dep't of Justice*, 185 F.3d 1035, 1041 (9th Cir. 1999).

Where FOIA contemplates expedited processing, the need for strict compliance with statutory deadlines "resounds with greater force." *Wash. Post v. Dep't of Homeland Sec.*, 459 F. Supp. 2d 61, 66 (D.D.C. 2006). Courts throughout the nation have thus granted judicial relief in an expedited fashion where FOIA's expedited processing criteria are met. *See ACLU v. Dep't of Def.*, 339 F. Supp. 2d 501 (S.D.N.Y. 2004); *Elec. Frontier Found. v. Office of the Dir. of Nat'l. Intelligence*, 542 F. Supp. 2d 1181 (N.D. Cal. 2008); *Elec. Privacy Info. Ctr. v. Dep't of Justice*, 416 F. Supp. 2d 30 (D.D.C. 2006); *Aguilera v. FBI*, 941 F. Supp. 144 (D.D.C. 1996); *Cleaver v. Kelley*, 427 F. Supp. 80 (D.D.C. 1976). "To afford [a] plaintiff less than expedited judicial review" of a request for expedited FOIA processing "would all but guarantee" that the statutory right to expedited disclosure would be lost. *Wash. Post*, 459 F. Supp. 2d at 66.

Resolution of this motion should be expedited because the FOIA criteria for expedited processing are amply satisfied, as will now be demonstrated.

II. PARTIAL SUMMARY JUDGMENT SHOULD BE GRANTED REQUIRING EXPEDITED PROCESSING OF SEIFE'S TARGETED FOIA REQUEST

A. Defendants' Denial of Expedited Processing Is Subject to *De Novo* Review by this Court, Applying the Standards Mandated by FOIA

Agencies are required by law to grant expedited processing for FOIA requests within ten days if the requestor demonstrates a "compelling need" for the information. 5 U.S.C. § 552(a)(6)(E)(i). FOIA declares that such a "compelling need" exists when a request is made "by

a person primarily engaged in disseminating information" and there is an "urgency to inform the public concerning actual or alleged Federal Government activity." 5 U.S.C. § 552(a)(6)(E)(v)(II). To determine whether an urgency to inform exists, courts in turn consider "(1) whether the request concerns a matter of current exigency to the American public; (2) whether the consequences of delaying a response would compromise a significant recognized interest; and (3) whether the request concerns federal government activity." *Al-Fayed v. CIA*, 254 F.3d 300, 310 (D.C. Cir. 2001); *see also Bloomberg v. U.S. Food & Drug Admin.*, 500 F. Supp. 2d 371 (S.D.N.Y. 2007) (following *Al-Fayed*).

In applying these standards, a denial of expedited processing is subject to *de novo* judicial review, without deference to an agency's conclusion that no "compelling need" is presented. 5 U.S.C. § 552(a)(6)(E)(iii); *see Wadelton v. Dep't of State*, 941 F. Supp. 2d 120, 122 (D.D.C. 2013); *Bloomberg*, 500 F. Supp. 2d at 374. Review is based on the administrative record before the agency "at the time of the determination." 5 U.S.C. § 552(a)(6)(E)(iii); *see ACLU N. Cal. v. U.S. Dep't of Def.*, No. 06-cv-01698 WHA, 2006 WL 1469418, at *1, *6 (N.D. Cal. May 25, 2006).

Here, defendants do not dispute that Seife is indeed "primarily engaged in disseminating information," and that the information he requested concerns an "actual or alleged Federal Government activity." 5 U.S.C. § 552(a)(6)(E)(v)(II); Kenney Decl., Ex. D. Defendants denied expedited processing solely because they do not see any urgent need to inform the public further about the troubling circumstances surrounding the Exondys 51 approval. Kenney Decl., Ex. D. Summary judgment on this issue is appropriate because there are no disputes of material fact and the record on which defendants made this determination is now entirely before this Court. *See* Fed. R. Civ. P. 56(c); Kenney Decl., Ex. D. In reviewing this record, the Court must of course draw

"all reasonable inferences" in defendants' favor, *Weinstock v. Columbia Univ.*, 224 F.3d 33, 41 (2d Cir. 2000) (internal citation and quotation omitted), but to defeat summary judgment they must "demonstrate more than some metaphysical doubt as to the material facts" and cannot rely on "allegations . . . or on conclusory statements, or on mere assertions that affidavits supporting the motion are not credible." *Purchase Partners v. Carver Fed. Savings Bank*, 914 F. Supp. 2d 480, 489 (S.D.N.Y. 2012) (Furman, J.) (internal citations and quotations omitted).

Upon the record before this Court, FOIA quite plainly requires expedited consideration of Seife's request, because this request does concern a matter of urgency to the public and the consequences of continuing delay would be significant.

B. FDA's Approval of Exondys 51 Is a Matter of Current Exigency to the American Public

Seife's request was plainly entitled to expedited treatment because it concerned a newsworthy agency action of "substantial interest" to the public that was "currently unfolding" when defendants denied expedited processing. *Al-Fayed*, 254 F.3d at 310-11. Whether a story is currently unfolding and of substantial interest may be demonstrated by evidence of widespread news reports, as well as by the agency's own acknowledgement of contemporary public interest. *See, e.g.*, *ACLU N. Cal.*, 2006 WL 1469418, at *6 (granting expedited processing in part because there were "at least fifty-three separate articles . . . in the fifty-two days immediately prior to the FOIA requests"); *ACLU v. Dep't of Justice*, 321 F. Supp. 2d 24, 28-31 (D.D.C. 2004) (finding compelling need based on widespread reporting and statements by the head of the agency that disclosure was in the public interest).

Interest by members of the legislative branch is also relevant in establishing public interest requiring expedition. *ACLU N. Cal.*, 2006 WL 1469418, at *2. It is demonstrated as well by debates over pending legislation and regulations. *ACLU v. Dep't of Justice*, 321 F. Supp.

2d at 30-31. And urgency can be shown by the "potential impact" of the information. *ACLU N. Cal.*, 2006 WL 1469418, at *7. Courts evaluate the totality of evidence, such that even if one factor is insufficient in and of itself to warrant expedited processing, in combination with other factors it might. *ACLU v. Dep't of Justice*, 321 F. Supp. 2d at 31.

Notably, and contrary to the position taken by defendants in denying Seife's administrative appeal, a request does not lose exigency merely because an initial wave of media attention given to an ongoing story crests before submission of a request. *Cf.* Kenney Decl. Ex. D, 3-4 (citing a decline in media attention given to Exondys 51 between its approval and Seife's request as evidence of a lack of exigency). A request remains currently exigent even when a great deal of information is already public, so long as "valuable, time-sensitive information apparently remain[s] unknown at the time of [a] plaintiff['s] request." *ACLU N. Cal.*, 2006 WL 1469418, at *7.

For instance, in *Bloomberg v. United States Food & Drug Administration*, this Court concluded that the FDA improperly denied expedited processing for a request related to anti-epileptic drugs that were the subject of national news reports. 500 F. Supp. 2d 371. There, the FDA publicly disclosed that it sent the manufacturers letters in March and April 2005 requesting information on the potential for these drugs to contribute to suicidal thoughts or actions. *Id.* at 373. Nearly a year later, in February 2006, Bloomberg submitted a FOIA request to the FDA for correspondence between the FDA and manufacturers of anti-epileptic drugs. *Id.* Bloomberg requested expedited processing, but the FDA denied the request and Bloomberg filed suit. *Id.* at 373-74.

Applying the first *Al-Fayed* factor, this Court reversed the FDA's denial. It held that the existence of national news reports of the FDA's initial inquiry to the manufactures demonstrated

that Bloomberg's request concerned a matter of current exigency to the American public. *Id.* at 373, 378. Significantly, this Court rejected the FDA's contention that there was no remaining urgency to inform the public of the FDA's correspondence with the manufacturers because the FDA had already publicly disclosed the initial communications. *Id.* at 377-78. Instead, this Court explained that the first *Al-Fayed* factor was satisfied with respect to any additional, unknown communications:

> Knowledge of the Initial FDA inquiry, of which the FDA claims the public has already been made aware, is not equivalent to knowledge of further inquiries by the Government, responses to those inquiries, and the attendant analysis of those results. Hence, an exigent need still exists with respect to the subsequent data received by the FDA from the drug manufacturers and with respect to the findings of the FDA.

Id. at 378.

So too here. Seife's request is related to a currently unfolding story of substantial interest to the public and the media, and time-sensitive, valuable information remains undisclosed. As such, the first *Al-Fayed* factor weighs in favor of Seife and expedited processing.

1. Currently Unfolding

Case law makes clear that a story is currently unfolding so long as news reports continue to be published up until the date of the initial request. For instance, in *American Civil Liberties Union of Northern California v. U.S. Department of Defense*, the court ordered expedited processing based, in part, on plaintiff's showing that, "[i]n the ten days leading up to the request, there were at least fourteen articles" published on the story at issue. 2006 WL 1469418, at *6. Other cases examine the media attention as a whole, accepting evidence from time periods of months prior to the request. *See, e.g., Gerstein v. CIA*, No. 06-cv-4643 MMC, 2006 WL 3462658, at *5 (N.D. Cal. Nov. 29, 2006) (granting expedited processing on the basis that there were 977 news reports in the ninety days prior to the request on the subject of the request).

Here, Seife's initial request cited the results of a Lexis Nexis news search for the word "eteplirsen" from January 1, 2016, through November 20, 2016, *i.e.* seventeen days prior to when Seife submitted his request on December 6, 2016. Kenney Decl., Ex. A. The search turned up 2272 articles. *Id.* at 10. That search was likely under-inclusive, as it did not include articles referencing only "Exondys 51." *See id.* In his administrative appeal, Seife submitted additional evidence demonstrating that between December 5, 2016, and February 3, 2017 (or three days before Seife submitted his administrative appeal), there were 150 articles published containing the word "eteplirsen" alone. Kenney Decl., Ex. C, n.1. Again, this figure was likely under-inclusive because it did not include articles using the trade name "Exondys 51," or articles in legal or scientific publications. *Id.*

FDA's denial of Seife's administrative appeal acknowledges that there were 296 news reports containing the words "eteplirsen" or "Exondys 51" published in the week after Exondys 51's approval, and twelve more reports published in the week before Seife's FOIA request. Kenney Decl., Ex. D, 4.[3] Those results are also likely under-inclusive as FDA "filter[ed] out articles with a high similarity." *Id.*

[3] The denial letter also indicated that some of these twelve articles did not mention the FDA's approval or mentioned the drug in passing. First, this assertion is impossible to verify because the FDA did not cite to any specific articles, as Seife has. Second, there is no evidence that searches in other cases were exclusively about the agency action in question; indeed, it is highly likely that they included articles about issues in general, not the agency. Third, even if the denial letter is correct, this does not diminish the news value of the information. For example, many articles are about Sarepta stock. But Sarepta stock relates directly to the approval of Exondys 51, as Dr. Woodcock acknowledged during the approval process, and it also relates to the veracity of clinical studies. Seife Decl. ¶¶ 15-18; Kenney Decl., Ex. P, 6, 53-54, 61-63, 84. Other articles mentioned by the FDA may discuss shareholder suits against Sarepta, but these, too, are relevant because they shed light on the "real world impact" of the approval, which is also relevant to the issue of delay, discussed *infra*; *see* Kenney Decl., Ex. C, 6 (citing Pl. Br. 44, *Cobran v. Sarepta Therapeutics*, Nos. 15-2135 & 16-1658 (1st Cir. Oct. 14, 2016), E.C.F. No. 37 (asserting that Sarepta defrauded its investors by misrepresenting trial results)); *see also* Kenney Decl., Ex. R (noting effect of Seife's complaint on Sarepta stock).

Even using the FDA's conservative numbers, Seife's request satisfies FOIA's "currently unfolding" requirement for expedited processing. There were at least twelve articles published in the seven days prior to Seife's request—an average of 1.7 articles a day as opposed to 1.4 articles a day introduced by the ACLU of Northern California in *American Civil Liberties Union of Northern California v. U.S. Department of Defense*, 2006 WL 1469418, at *6; Kenney Decl., Ex. D. And the FDA does not provide a standard for the number of articles it deems necessary for expedited processing, a standard that appears impossible to meet given just two grants over FYs 2014 and 2015, each of which took over four hundred days to process. *See supra* 8 & note 2.

2. Substantial Interest

Seife's request clearly relates to a matter of substantial interest to the American public. In his initial request, Seife cited post-approval articles about Exondys 51 from national publications, including articles published in *Forbes*, *The New York Times*, *The Washington Post*, *NPR*, and *STAT News* (a news site run by the *Boston Globe*). Kenney Decl., Ex. P, 2-47. Seife's FOIA appeal cited additional publications from other media outlets with similarly wide readerships. *Id.* at 53-56, 60-68, 72-84. For instance, Seife cited a December 23, 2016, article published in the *Wall Street Journal*, describing Exondys 51's approval as an example of the "FDA Empire Strik[ing] Back." *Id.* at 72-73. In addition, a member of the Advisory Committee who voted against the approval of Exondys 51 supported Seife's FOIA appeal, explaining that the integrity of the FDA is a story of importance to the American public who care about the "decisionmaking of the national drug regulator." Kenney Decl., Ex. M.

As in *American Civil Liberties Union v. Department of Justice*, the agency's own actions surrounding Exondys 51's approval indicate the substantial public interest in the matter. The FDA conducted a sui generis appeal process to review Dr. Woodcock's veto of the review team's recommendation. Kenney Decl. Ex. E, n.5. Former FDA Commissioner Califf issued a public

call for the retraction of the published results of Study 201/202. Kenney Decl. Ex. E, n.28. The top member of the clinical team in the neurology products division promoted public awareness of the internal conflicts at the FDA by leaving the agency shortly before the approval was announced. *See* Kenney Decl. Ex. P, 11-13 (noting critic's known opposition to the approval of Exondys 51 and the media's reaction to his departure). And, in the aftermath of Exondys 51's approval, the FDA not only released the approval package for the drug, as is standard for all drugs; it also took the extraordinary step of making public all of the documents surrounding Dr. Unger's appeal of Dr. Woodcock's decision to grant approval. Kenney Decl., Exs. E-J.

3. Time-Sensitive, Valuable Information Remains Unknown

As in *Bloomberg*, and contrary to the FDA's administrative denial letter, Seife's request remains exigent notwithstanding the widespread coverage of the FDA's approval because time-sensitive information remains unknown that is valuable to the public and the media. *See* 500 F. Supp. 2d 371. Information obtained through Seife's request would also have a real-world impact on the behavior of families of children with Duchenne, their doctors, and insurance companies; the FDA as an institution; legislative and regulatory actions; the pending review of Exondys 51 in Europe; and Sarepta's capitalization.

First, the information Seife seeks would significantly affect public health by indicating whether Exondys 51 actually works. Seife Decl. ¶ 16. Information demonstrating the effectiveness of Exondys 51 is time-sensitive and valuable. If Exondys 51 is not effective, the information Seife seeks would demonstrate that children are taking a drug that is ineffective and which may pose a risk of infection and even death. Kenney Decl., Ex. G, 21-22. The sooner this information comes to light, the sooner these health risks can be properly included in doctors' determinations as to whether to prescribe the drug to patients, and included in families' decisions whether to undergo financial hardship—and potential loss of homes and other significant

financial toxicities—to pay for the $300,000 plus a year drug. *Cf. id.* (describing safety risks); *see also* Kenney Decl., Ex. M (describing doctor responses). If the information demonstrates that Exondys 51 is in fact effective and safe, insurers will likely start covering the drug and families may be more inclined to have their children take the drug. Kenney Decl., Ex. M.

Second, there are open questions about the institutional integrity of the FDA and whether the head of the Center for Drug Evaluation and Research or her staff were subject to undue influence by the very drug company seeking their approval. Seife Decl. ¶ 15. The correspondence Seife seeks would shed light on that issue and reveal whether considerations that are irrelevant to the statutory drug-approval requirements of accelerated approval are shaping the approval process. *Id.* The public needs to know the basis of approval for the drugs they take and whether the approval process is valid as soon as possible.

Third, the information Seife seeks may influence upcoming legislation. At the time of the FOIA appeal, the then-President Elect's potential FDA nominees announced they were considering speeding up the drug approval process. Kenney Decl., Ex. P, 69-71. Because the requirements for accelerated approval are statutory, 21 U.S.C. §§ 356(c), changing them necessitates action by Congress. Congress is also considering the Prescription Drug User Fee Act (PDUFA), which must be reauthorized in 2017, and is likely to be a vehicle for some of these changes, including patient input. Kenney Decl., Ex. P, 51-52. The information Seife seeks is likely to affect these debates, as the approval of Exondys 51 has become the prism through which approvals are analyzed. *See id.* at 66-68, 72-73; *see also* Kenney Decl., Ex. C.

Fourth, the information is likely to influence the behavior of the FDA in drafting regulations as mandated by the 21st Century Cures Act. The Act requires agencies to issue rules governing the use of "patient experience"—*i.e.* the self-reporting of patients regarding the

efficacy and safety of the drugs they take—in the approval process. 21 U.S.C. § 360bbb-8c. This evidence is notoriously unreliable because it does not account for the placebo effect, Kenney Decl. Ex. N, and the information Seife requested will show how patient testimonials influenced the FDA, and in particular the head of Center for Drug Evaluation and Research, Dr. Woodcock, in the Exondys 51 approval process as a case study of the dangers of caving in to public pressure. Seife Decl. ¶ 15. Disclosure of the information Seife seeks would likely affect the FDA's decisions about how to treat patient testimonials in the future and what weight to accord them if the clinical evidence shows the drug had no effect.

Fifth, the information Seife seeks could influence the European Medicines Agency's (EMA) review of the drug. As Dr. Kesselheim explains:

> The information sought could influence whether the EMA approves the drug for use in Europe. If the information is released in time, it could reveal that political pressures led to the drug's approval despite major flaws in the pivotal studies. Under these circumstances, the EMA—which typically examines the same studies the FDA uses for approval and can be influenced by the FDA's decision-making—might hesitate to approve the drug. By contrast, it could reveal aspects of the FDA's deliberative process that provide greater support for the drug's effectiveness and safety, which could lead the EMA to be more likely to approve the drug.

Kenney Decl., Ex. M. If the EMA approves the drug, the decision could lead "to use of the drug by thousands of more children." *Id.* The EMA has 210 days to consider the drug, not counting time for answers to its questions, and the clock started ticking in late December 2016. Kenney Decl., Ex. P, 74-81.

Finally, Exondys 51 is the principal product made by Sarepta and the company's financial survival is tied to it, as has been evidenced by shareholder suits filed in the wake of certain disclosures about the efficacy of the drug. *See supra* note 3. According to one media report, Sarepta's stock plunged 18 percent simply on the news that this lawsuit had been filed.

Kenney Dec., Ex. R. The requested information, then, is even more likely to affect Sarepta stock and legal liability, which is newsworthy and of urgent importance to the public.

As in *Bloomberg*, each of these factors clearly dictates that "an exigent need still exists" for disclosure of the requested information, notwithstanding the widespread coverage of Exondys 51's approval. 500 F. Supp. 2d at 378; *see also ACLU N. Cal.*, 2006 WL 1469418, at *7 (explaining that the fact that "a great deal of information [is] already public" about a story "eliminate[s] urgency only if *all* major news . . . ha[s] been reported, *i.e.*, if there [is] nothing more to say").

C. Delaying A Response To Seife's Request Compromises Significant Recognized Interests

The second *Al-Fayed* factor, whether delayed release would compromise significant recognized interests, also weighs in Seife's favor. Indeed, some courts consider the "delay" aspect of the test "really a subpart of the first issue because it defines what types of materials can be 'urgently needed.'" *ACLU N. Cal.*, 2006 WL 1469418, at *6 (citation omitted).

This Court has already recognized that "harm to the health of the public . . . if sustained use of [a drug] continues without more immediate guidance and information from the FDA" constitutes a significant recognized interest for purposes of the second *Al-Fayed* factor. *Bloomberg*, 500 F. Supp. 2d at 378. Other courts have recognized that significant interests include the media's interest in quickly disseminating breaking, general-interest news, *ACLU N. Cal.*, 2006 WL 1469418, at *8, and in "enhancing public debate on potential legislative action," *Gerstein*, 2006 WL 3462658, at *7.

Seife and the public will be precluded "from obtaining in a timely fashion information vital to the current and ongoing debate surrounding the legality of" the FDA's actions, the effectiveness of a hugely costly drug, and debates surrounding upcoming legislation. *Elec.*

Privacy Info. Ctr., 416 F. Supp. 2d at 41. Indeed, delay in processing Seife's request "may well result in disclosing the relevant documents *after* the need for them in the formulation of national . . . policy has been overtaken by events." *See Nat. Res. Def. Council v. Dep't of Energy*, 191 F. Supp. 2d 41, 43 (D.D.C. 2002) (emphasis in original) (granting motion for release of documents). Moreover, depriving Seife of his right to review the documents he requests inhibits him from expressing an informed opinion on the ongoing debate. *Cf. Elrod v. Burns*, 427 U.S. 347, 373 (1976) ("The loss of First Amendment freedoms, for even minimal periods of time, unquestionably constitutes irreparable injury.").

Delayed disclosure could compromise each of these significant recognized interests. Delayed disclosure of the information Seife seeks could harm the public health. As noted above, the information Seife seeks is likely to reveal whether Exondys 51 is in fact effective. If the drug is proven ineffective, doctors are likely to cease prescribing the drug and families are unlikely to go into deep debt to pay for an ineffective drug. If the drug is proven effective, insurers are likely to start covering the drug, ensuring that many more can afford its cure. Disclosure is likely to affect the European Medicine Agency's pending approval of the drug, either ensuring that thousands more do not pay for an ineffective drug, or that they obtain an effective treatment.

Delayed disclosure would also prevent Seife and others from disseminating breaking, general-interest news. As noted above, Exondys 51's approval received widespread attention. Confirmation or refutation of its effectiveness or news of additional problems with FDA's approval will undoubtedly receive similar attention and garner widespread attention.

Delayed disclosure also inhibits debate on potential legislative and regulatory action. Upcoming legislative debates on reauthorization of the Prescription Drug User Fee Act, FDA's implementation of the 21st Century Cures Act, and any steps the FDA takes to alter its

accelerated approval process will all be significantly impacted by disclosure of information revealing flaws in Exondys 51's approval.

For all of these reasons, the second *Al-Fayed* factor, like the first, weighs strongly in favor of Seife. Because both factors plainly favor Seife, Seife is likely to succeed on the merits of his request for expedited processing.

D. Defendants Other Arguments Are Unavailing

This Court should explicitly reject the FDA's position that a mere decline in the volume of news reports eliminates exigency and that the expedited processing should not be granted because Seife delayed by filing his request two and a half months after the approval, if FOIA's expedited processing requirements are to be useful in serving the public interest. Serious investigative journalism takes time. Seife Decl. ¶¶ 19-20. It takes time to identify sources, and to draft specific, relevant, and targeted FOIA requests. *Id*. Seife, for example, spoke to confidential sources who helped identify FDA records containing information that would make for highly topical news stories and inform the public debate. *Id.* ¶¶ 5-7. Seife would not have had the time to undertake such a thorough investigation had he been required to file in a week, or a month, or a month and a half, or whatever arbitrary deadline a court might choose to impose. *Id.* ¶¶ 19-20. Further, although Seife waited approximately two and a half months after approval to file the FOIA request, he only waited slightly more than one month after all of the FDA's documents on the disputes were made public, on October 26, 2016. *See supra* n.1. If the mere decline in the volume of news reports FDA identified in its administrative denial letter is sufficient to defeat a request for expedited processing, FOIA's expedited processing provision is effectively useless to serious investigators like Seife.

In addition, the principal case on which the defendants rely, *Treatment Action Group v. U.S. Food & Drug Administration,* No. 15-cv-976, 2016 WL 5171987, at *9 (D. Conn. Sept. 20,

2016), considered the fact that the FOIA request was made a year after the approval of one of the drugs at issue, and the second drug at issue was approved two months before the FOIA request. Other more persuasive cases denying expedited processing, including the only Court of Appeals case, use timeframes of years rather than months. *Al-Fayed* rejected a request for information about the death of Princess Diana because her death had occurred two to three years prior to the request. 254 F.3d at 300; *see also Wadelton*, 941 F. Supp. 2d at 123 (denying request when made two to three years after events transpired); *Tripp v. Dep't of Def.*, 193 F. Supp. 2d 229, 242 (D.D.C. 2002) (denying request because it was made three years after the event in question transpired). In contrast, in *Gerstein v. CIA*, the court granted expedited processing when the FOIA *request* was filed at least six months after the discovery of surveillance programs and leaks at issue in the request. 2008 WL 4415080, at *1.

CONCLUSION

For the foregoing reasons, Seife respectfully requests an order (1) requiring defendants to provide a full written response to the request within ten days, and (2) setting a status conference within twenty days to establish a schedule for the expedited release of the requested information on a rolling basis. In light of the time-sensitive nature of his FOIA request, Seife also respectfully requests that the Court expedite consideration of this motion pursuant to 28 U.S.C. § 1657.

Dated: June 21, 2017
New York, NY

Respectfully submitted,

MEDIA FREEDOM & INFORMATION ACCESS CLINIC[4]

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[4] This memorandum has been prepared by the Media Freedom and Information Access Clinic, a program of the Abrams Institute for Freedom of Expression at Yale Law School. Nothing in this memorandum should be construed to represent the institutional views of the law school, if any.

TABLE OF DECLARATIONS AND EXHIBITS

Declarations

Declaration of Charles Seife dated June 21, 2017
Declaration of Cortelyou C. Kenney dated June 21, 2017

Exhibits

Key Documents in Case	
Exhibit A	Freedom of Information Act (FOIA) Request to the Food and Drug Administration (FDA), mailed on December 6, 2016 (dated Dec. 5, 2016).
Exhibit B	Email Attachment from FDA Denying Expedited Processing of December 6 FOIA (Dec. 21 2016).
Exhibit C	Freedom of Information Act Appeal, Reference Number 2016-10322 to the Department of Health and Human Services (HHS) (Feb. 6, 2016).
Exhibit D	Email Attachment from FDA Denying Appeal (April 25, 2017).
Excerpts from Agency Documents	
Exhibit E	Robert Califf, *Scientific Dispute Regarding Accelerated Approval of Sarepta Therapeutics' Eteplirsen (NDA 206488-Commissioner's Decision* (Sept. 16, 2016), *in* Center for Drug Evaluation and Research Summary Review 2 (2016), http://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/206488Orig1s000SumR.pdf.
Exhibit F	Luciana Borio, *Scientific Dispute Resolution Appeal regarding Eteplirsen*, *in* Center for Drug Evaluation and Research Summary Review 15 (2016), http://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/206488Orig1s000SumR.pdf.
Exhibit G	Ellis Unger, *Agency Scientific Dispute – Appeal*, *in* Center for Drug Evaluation and Research Summary Review 42 (2016),

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Exhibit H	Janet Woodcock, *Center Director Decisional Memo*, *in* Center for Drug Evaluation and Research Summary Review 69 (2016), http://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/206488Orig1s000SumR.pdf.
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Exhibit J	Xiang Ling et al., *Statistical Review for NDA206488*, *in* FDA Briefing Document, Peripheral and Central Nervous System Drugs Advisory Committee Meeting, April 25, 2016, NDA 206588, Eteplirsen 95 (2016), http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/PeripheralandCentralNervousSystemDrugsAdvisoryCommittee/UCM497063.pdf.
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Exhibit K	View of NCT01396239 (July 15, 2011), https://clinicaltrials.gov/archive/NCT01396239/2011_07_15, and View of NCT01396239 (Nov. 6, 2015), https://clinicaltrials.gov/archive/NCT01396239/2015_11_06.
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Exhibit L	Jett Foundation, *109 Congressional Representatives Stand with Duchenne* (Feb. 18, 2016).
Kesselheim Letter	
Exhibit M	Letter from Dr. Aaron Kesselheim, Associate Professor of Medicine at Harvard Medical School, to Catherine Teti, Deputy Agency Chief FOIA Officer at the U.S. Department of Health & Human Services (Jan. 31 2016).
Kesselheim JAMA Piece	
Exhibit N	Aaron S. Kesselheim & Jerry Avorn, *Approving a Problematic Muscular Dystrophy Drug: Implications for FDA Policy*, JAMA (Dec. 13, 2016).

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Exhibit O	Charles Seife, *How to Sp!n The Science News*, Scientific American, Oct. 2016, 54, pp. 2-9.
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Exhibit Q	Letter from FDA to Charles Seife Acknowledging FOIA Request, dated December 14, 2016, pp. 2-3.
	Letter from Glenn Voelker, Department of Health and Human Services, Office of FOIA Services, Office of the Secretary, Assistant Secretary for Public Affairs to Charles Seife acknowledging FOIA Appeal, dated February 8, 2017, p. 4.
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CERTIFICATE OF SERVICE

I certify that on June 21, 2017, this Memorandum was filed with the Clerk of the Court using the Court's CM/ECF docketing system, which will mail a copy of all counsel of record capable of receiving electronic pleadings. Parties may access this filing through that system.

/s/ David Schulz
David Schulz